

What is claimed is:

1. A device for sampling a bodily fluid from an incision in skin, comprising:
a lancet to form the incision in the skin;
5 a housing coupled to the lancet, the housing defining at least in part a capillary channel
with an opening, the capillary channel being sized to draw the bodily fluid from the incision
via capillary action; and
a flexible sheet extending from the housing proximal the opening of the capillary
channel to draw the bodily fluid into the opening of the capillary channel.
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2. The device of claim 1, wherein the housing defines a notch at the opening of
the capillary channel to minimize dose hesitation of the bodily fluid into the capillary
channel.
- 15 3. The device of claim 1, wherein the sheet is hydrophilic for enhancing the flow
rate of the bodily fluid into the capillary channel.
4. The device of claim 3, wherein the sheet is coated with a hydrophilic coating.
- 20 5. The device of claim 4, wherein the hydrophilic coating includes aluminum
oxide.
6. The device of claim 1, wherein the sheet is transparent for allowing a user to
view the bodily fluid while being drawn into the capillary channel.
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7. The device of claim 1, wherein:
the housing has an outside surface; and
the lancet is attached to the outside surface of the housing.

5 8. The device of claim 7, wherein the lancet is glued to the outside surface of the housing.

9. The device of claim 1, wherein the housing defines a registration opening for positioning the housing.

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10. The device of claim 1, wherein:
the housing includes a base and a spacer member attached to the base;
the spacer member defines a slot;
the sheet covers at least a portion of the slot; and

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the spacer member is sandwiched between base and the sheet to form the capillary channel in the slot.

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11. The device of claim 10, wherein the housing includes a cover covering the sheet over the slot and a vent member defining a vent opening for exhausting gas from the capillary channel.

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12. The device of claim 11, further comprising a test area positioned along the capillary channel in which the bodily fluid is analyzed, wherein the vent opening is defined between the test area and the vent member.

13. The device of claim 12, wherein the test area includes a reagent test strip.

14. The device of claim 10, further comprising a test area positioned along the capillary channel for analyzing the bodily fluid.

15. The device of claim 1, wherein the lancet includes a lancet tip that extends
5 from the housing past the opening of the capillary channel to form the incision.

16. The device of claim 15, wherein the lancet tip has a triangular shape.

17. The device of claim 15, wherein the lancet tip has a slanted shape.
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18. The device of claim 15, wherein the lancet tip defines a slot for drawing the bodily fluid into the capillary channel.

19. The device of claim 15, wherein the sheet extends past the lancet tip in order
15 for the sheet to remain in contact with the skin and draw the bodily fluid when the lancet tip is removed from the skin.

20. The device of claim 1, wherein the housing and the lancet are flat.

20 21. The device of claim 1, further comprising means for testing the bodily fluid in the capillary channel.

22. The device of claim 21, wherein the means for testing the bodily fluid includes a reagent test strip.

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23. The device of claim 1, further comprising a testing system positioned along the capillary channel to analyze the bodily fluid.

24. The device of claim 23, wherein the testing system includes a reagent test strip.

25. The device of claim 23, wherein the testing system includes:

5 at least two electrodes; and
an electrochemical test strip positioned between the electrodes in the capillary channel.

26. The device of claim 25, wherein the housing includes:

a base made of insulating material, the electrodes extending along the base; and
10 a spacer made of insulating material, the electrodes being sandwiched between the
base and spacer, the spacer defining a slot, wherein said sheet covers the slot to form the
capillary channel.

27. The device of claim 23, wherein:

15 the sheet is hydrophilic; and
the sheet extends along the capillary channel to draw the bodily fluid onto the test
system.

28. The device of claim 1, wherein the housing has a skin contact surface that is

20 shaped to maintain the incision open as the housing is pressed against the skin.

29. The device of claim 28, wherein the skin contact surface and the housing are
beveled.

25 30. The device of claim 1, further comprising a second flexible sheet extending
from the housing on the opposite side of the capillary channel as the flexible sheet to draw
the bodily fluid into the opening of the capillary channel without closing the incision.

31. The device of claim 30, wherein the flexible sheet and the second flexible sheet face each other.

5 32. A method of sampling a bodily fluid from an incision in skin, comprising:
providing a device that includes a housing that defines a capillary channel with an
opening, a lancet coupled to the housing, and a flexible sheet that extends from the housing
proximal the opening of the capillary channel;
lancing the incision in the skin with the lancet; and
10 drawing the bodily fluid from the incision into the capillary channel with the sheet.

33. The method of claim 32, wherein:
the lancet includes a lancet tip extending from the housing proximal the opening of the
capillary channel; and
15 said drawing includes retracting the lancet tip from the skin to a position with the sheet
remaining in contact with the skin

34. The method of claim 33, further comprising:
wherein the device includes testing means positioned along the capillary channel;
20 depositing the bodily fluid in the capillary channel onto the testing means; and
analyzing the bodily fluid with the testing means.

35. The method of claim 34, wherein said analyzing includes chemically testing
analyte levels in the bodily fluid.

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36. The method of claim 34, wherein said analyzing includes electrochemically
testing analyte level in the bodily fluid.

37. The method of claim 32, further comprising:
wherein the device includes testing means positioned along the capillary channel;
depositing the bodily fluid in the capillary channel onto the testing means; and
5 analyzing the bodily fluid with the testing means.

38. An integrated bodily fluid sampling device for sampling a bodily fluid from an
incision in skin, comprising:
a housing defining a capillary channel with an opening;
10 a flat lancet slidably received in the channel, the lancet having a lancet tip configured
to form the incision in the skin, the lancet tip having a first position at which the lancet tip is
positioned inside the housing and a second position at which the lancet tip extends from the
opening of the channel to form the incision in the skin;
means for testing the bodily fluid positioned along the channel; and
15 wherein the capillary channel is sized to draw via capillary action the bodily fluid from
the incision around the lancet and onto the means for testing the bodily fluid.

39. The device of claim 38, further comprising a retraction mechanism coupled
between the housing and the lancet tip to move the lancet tip from the second position to the
20 first position after forming the incision in the skin.

40. The device of claim 39, wherein the retraction mechanism includes a spring
arm defined by a pair of opposing notches in the lancet.

25 41. The device of claim 39, wherein the retraction mechanism includes a leaf
spring.

42. The device of claim 38, wherein the means for testing the bodily fluid includes a reagent test strip.

43. The device of claim 38, wherein the lancet tip has a triangular cross-sectional
5 shape.

44. The device of claim 38, wherein the housing defines a notch at the opening of the channel for minimizing dose hesitation of the bodily fluid into the opening.

10 45. The device of claim 38, wherein the housing has a skin contacting edge positioned at the opening of the channel for providing a reference surface for control penetration depth of the lancet tip into the skin.

46. The device of claim 45, further comprising a penetration depth adjustment
15 mechanism coupled to the housing for adjusting the penetration depth of the lancet tip into the skin.

47. An integrated bodily fluid sampling device for sampling a bodily fluid from an incision in skin, comprising:

20 a housing defining a capillary channel with an opening configured to draw the bodily fluid via capillary action;

a lancet having a lancet tip for forming the incision in the skin, the lancet being attached to the housing with the lancet tip extending from around the opening of the channel, the lancet being immovable with respect to the housing; and

25 means for testing the bodily fluid positioned along the channel.

48. The device of claim 47, wherein the means for testing the bodily fluid includes a chemical reagent test strip.

49. The device of claim 47, wherein the means for testing the bodily fluid at least a pair of electrodes and an electrochemical reagent spanning between the electrodes.

50. The device of claim 47, further comprising a sheet of hydrophilic film extending from the opening of the channel for drawing the bodily fluid into the channel.

51. The device of claim 47, wherein the lancet has a flat shape.

52. The device of claim 47, wherein the housing includes:
a base;
a cover; and
a spacer sandwiched between the base and the cover to define the channel.

53. The device of claim 52, wherein the lancet, the base, the cover and the lancet have an overall flat shape.

54. The device of claim 47, wherein the housing defines a notch at the opening of the channel for minimizing dose hesitation of the bodily fluid into the opening.